IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION

UNITED STATES OF AMERICA, Plaintiff, ex rel. JON VITALE, Relator, v. MIMEDX GROUP, INC., Defendant.	CA No. 3:17-cv-00166-RBH

Relator's memorandum in opposition to Defendant's motion to dismiss

This action arises from a cynical scheme by Defendant MiMedx Group, Inc. (MiMedx) to manipulate the submission of patient assistance program (PAP) grant applications to a third-party charitable organization to ensure that receipt and acceptance of applications from patients seeking coinsurance assistance for its biological products coincides with contributions by MiMedx to the charity, the effect of which is to ensure MiMedx's so-called charitable contributions are used to subsidize the cost of coinsurance payments that might otherwise foreclose use of its products and reimbursement by federal health insurance programs.

This scheme violates the Anti-Kickback Statute (AKS), 42 U.S.C. § 1320-7b, which makes it a crime to knowingly and willfully offer or pay any remuneration to induce the referral of business reimbursable under a federal health benefits program, and directly implicates concerns in the Department of Health and Human Services' Office of the Inspector General (HHS-OIG) and its most recent regulatory guidance on PAP charitable funds. This kickback scheme also causes

the submission of materially false claims for payment, actionable under the False Claims Act (FCA), 31 U.S.C. §§ 3729 et seq., and this action seeks to recoup treble damages and statutory penalties (among other relief) to compensate the federal treasury for the cost of this fraud.

MiMedx contends this action should be dismissed because the Complaint falls short of the pleading requirements imposed by Rule 9(b) of the civil rules and because it is barred by the FCA's public disclosure bar. See Dkt. No. 65. Neither contention is correct. Relator Jon Vitale has described the who, what, when, and how of the fraud. These allegations are particular and plausible because they are backed by his personal, first-hand knowledge as a former sales rep for the company and MiMedx's own records. See generally, Dkt. No. 1. Were there any doubt that this scheme has resulted in the submission of false claims, included within the allegations is a *specific* example of a patient whose Medicare Part D coinsurance payment was paid as a result. See Dkt. No. 1 at ¶ 156 & Dkt. No. 1-7 (Ex. G)). As explained below, this level of specificity is *always* sufficient to allow a relator's FCA claim through the courthouse doors. MiMedx's public disclosure bar argument is also misplaced because the purported disclosure is not a "public disclosure" within the meaning of 31 U.S.C. § 3730(e)(4) and, even if it were, the essential elements of this claim—MiMedx's manipulation of a PAP charitable fund ensure its "charitable" giving facilitated reimbursement by federal health insurance programs—is absent from the earlier civil action. The motion should be denied.

FACTUAL AND PROCEDURAL BACKGROUND

On January 19, 2017, Mr. Vitale filed this action under seal, pursuant to 31 U.S.C. § 3730, seeking to recover monies illegally obtained by MiMedx from federal health insurance programs through the sale of regenerative biomaterials in violation of the AKS. See Dkt. No. 1. In short, MiMedx secures reimbursement of its products by illegally paying co-pays and coinsurance for

federally insured patients and disguising the illegal payments as "charitable" contributions to a PAP—the Patient Assistance Network Foundation (PAN Foundation)—while manipulating the submission of patient assistance applications to ensure its contributions only fund patients seeking MiMedx products. See Dkt. No. 1 at ¶¶ 115–59.

Of particular concern here is the manner in which MiMedx coordinated the submission of patient assistance applications by sales reps like Mr. Vitale with the company's so-called charitable contributions to PAN Foundation's Diabetic Foot Ulcers (DFU) and Venous Leg Ulcers (VLU) funds. When funded by third-party giving, these funds remain open until exhausted by patient need. See id. ¶ 112. Beginning in February 2014, company executives began alerting reps of when the funds would open. Id. ¶¶ 120–21.

> In an email send in late February 2014, Roselli told reps that MiMedx would be funding PAN Foundation in the near future, would inform reps when the fund opened, and that they should begin collecting the names of possible patient applicants. In other words, whereas reps were previously instructed to submit PAN Foundation names as quickly as possible, beginning in February 2014, MiMedx would coordinate its contributions to the funds with reps' submission of patient applications.

Id. ¶ 122. By April 2014, MiMedx was matching its charitable contributions to the total patient need as identified by sale reps collecting patient assistance applications in the field. See id. ¶¶ 126–27. "Instead of submitting applications immediately, Mr. Vitale and his colleagues held this patient information until they received notice from MiMedx the fund would open." Id. ¶ 138. MiMedx executives determined the size of the contribution necessary to subsidize MiMedx products based on the number of PAP applications collected by reps and reported to MiMedx management via weekly emails and sometimes text messages. See id. ¶¶ 148–52 ("[T]these weekly rep field reports concerning PAN Foundation applicants that could be rushed into the pipeline were 'rolled up' to regional sales directors (RSD) who, in turn, created regional reports sent to MiMedx's regional

vice presidents for regions East, Midwest, and West, thus alerting executive management to the exact number of PAN Foundation applicants that would be seeking approval for MiMedx products."). When MiMedx management decided to contribute to the DFU and VLU funds, reps received advance email notice, sometimes days ahead of time, that the funds would soon open, so they could quickly submit patient assistance applications to PAN Foundation and exhaust the recently contributed MiMedx funds. See id. ¶¶ 131–45. Examples of these email communications are attached to the Complaint. See, e.g., Dkt. No. 1-3, 1-5 & 1-6.

The Complaint also includes allegations and documentary evidence detailing how this scheme worked with one patient identified as "Jane Doe." Mr. Vitale has alleged:

> For example, on August 11, 2015, PAN Foundation faxed a letter to Dr. Raymond Corpe, an orthopedic surgeon then at Palmetto Health Advanced Wound Care, concerning his patient, Jane Doe, informing Dr. Corpe that Ms. Doe would receive a $3,500 grant reimbursing the cost sharing (i.e., coinsurance) associated with "specific, out-of-pocket ***medication*** expenses related to Lower Extremity Ulcers." See Ltr. from PAN Foundation to Dr. Corpe (emphasis original) (attached as **Exhibit G**). Included in the letter is a Pharmacy Control Number (PCN) for Medicare Part D, indicating Jane Doe is insured through Medicare Part D.

Dkt. No. 1 at ¶ 156 (emphasis original, footnote omitted). MiMedx reps routinely received confirmation letters, like the one sent concerning Jane Doe (and attached to the Complaint (Dkt. No. 1-7 (Ex. G)), which enabled them to notify clinic staff of the PAN Foundation's grant approval and follow up to schedule the procedure. Dkt. No. 1 at ¶ 157. Mr. Vitale estimates an average of 25 or more PAN Foundation grants per year to his customers' patients, but that colleagues with a greater number of commercial accounts in their portfolio likely had far more. See id. ¶ 158; see also id. ¶ 61 (identifying Mr. Vitale's 15 commercial accounts). "Companywide, this scheme is believed to have resulted in approximately 7,500 patient assistance grants from PAN Foundation to patients seeking the use of MiMedx product." Id. ¶ 159.

ARGUMENT

MiMedx's seeks dismissal under four theories, two of which can be dispensed with at the outset. First, the drug company reads the Complaint to join claims arising from allegations that MiMedx offered improper remuneration to physicians in the form of meals, speakers' fees, and a reimbursement guarantee and argues any claims arising from this conduct is insufficiently plead. See Dkt. No. 65-1 at 7, 10 & 18–19. To be sure, MiMedx has engaged in *many* corrupt and illegal schemes, some of which are the subject of litigation in this District[1] and elsewhere.[2] But the FCA claims joined here arise from the PAP-manipulation scheme detailed in the Complaint. To the extent MiMedx's seeks to defend some other set of allegations, it misconstrues the nature of this action and reads too much from language intended to set scene for the operative fraud at issue.

Second, MiMedx argues the Federal Employees Health Benefits Plan (FEHBP)—a private insurance program run by the U.S. Office of Personnel Management—is excluded from the kickback prohibitions in the AKS. See Dkt. No. 65-1 at 21–22 (citing 42 U.S.C. § 1320a-7b(f) (excluding from the definition of "federal health care programs" any program enacted under chapter 89 of Title 5)). MiMedx is correct—the AKS does not apply to the FEHBP and therefore those claims cannot go forward here and should be dismissed.

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[1] See United States v. Becker et al., No. 6:18-cr-481 (D.S.C.) (D.S.C.) (indicting three employees of the U.S. Department of Veteran's Affairs for bribery by MiMedx employees).

[2] See, e.g., Abrams v. MiMedx Group, Inc., 37 F.Supp.3d 1271 (N.D. Ga. 2014) (denying motion to dismiss shareholder class action); Kruchoski v. MiMedx Group, Inc., 0:16-cv-04171-RHK-BRT (D. Minn.) (alleging MiMedx deceived investors by overstating accounts receivable with a "channel stuffing" scheme); see also David Allison, "MiMedx says ex-CEO Parker Petit, other execs engaged in 'conduct detrimental to the business,'" ATLANTA JOURNAL CONSTITUTION, Sept. 21, 2018 (reporting the drug maker was "rocked" by an internal investigation into sales and distribution practices and the indictment of three VA employees).

MiMedx's remaining contentions challenge the particularity of the allegations and argue this action is the product of a disqualifying public disclosure. These arguments are addressed in turn and should be rejected.

I. The Complaint is particularly plead because it outlines the who, what where, when and how of the fraud using company records, allegations from a witness to the scheme, and an individual claim made to the Medicare Part D program.

The FCA imposes treble damages and civil penalties against any person who, *intra alia*, "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A) (emphasis added). The FCA's reach is long as the section establishing liability for false claims is designed to encompass "all types of fraud, without qualification, that might result in financial loss to the Government[.]" Harrison v. Westinghouse Savannah River Co., 176 F.3d 776, 788 (4th Cir. 1999) (Harrison I) (quoting United States v. Neifert–White Co., 390 U.S. 228, 232 (1968)). "Thus, any time a false statement is made in a transaction involving a call on the U.S. fisc, False Claims Act liability may attach." Id. But when "alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Rule 9(b)'s particularity requirement applies to FCA claims, which, at their essence, sound in fraud. Harrison I, 176 F.3d at 783–84.

MiMedx questions whether the Complaint meets this heightened pleading requirement but misunderstands what Rule 9(b) requires by confusing that heighted pleading standard with Rule 8's plausibility requirement—a threshold standard in *every* federal action. See, e.g., Dkt. No. 65-1 at 11–12 (arguing Mr. Vitale has failed to meet his burden under Rules 9(b) and 12(b)(6) to allege "Particularized Facts *Plausibly* Showing a Violation of the False Claims Act." (bold removed, emphasis added)). The error of this approach is addressed first, followed by MiMedx's more specific contentions thereafter.

A. Particularity and plausibility are distinct analytical concepts.

The legal sufficiency of a complaint is measured by whether it meets the general rules of pleading set forth in Rule 8, the special rules of pleading set forth in Rule 9, and Rule 12(b)(6)'s requirement that a complaint state a claim for which relief can be granted. Francis v. Giacomelli, 588 F.3d 186, 192 (4th Cir. 2009). Rule 8 merely requires "a short and plain statement of the claim showing that the pleader is entitled to relief[.]" Fed. R. Civ. P. 8(a)(2). This general rule has been construed to include a plausibility requirement that asks whether the pleader has pled "enough factual matter (taken as true) to suggest" that the alleged illegality occurred. See Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555–56 (2007). "The determination whether a complaint adequately states a plausible claim is a 'context-specific task,' in which the factual allegations of the complaint must be examined to assess whether they are sufficient 'to raise a right to relief above the speculative level.'" Walters v. McMahen, 684 F.3d 435, 439 (4th Cir. 2012) (quoting Ashcroft v. Iqbal, 556 U.S. 662, 679 (2009), and Twombly, 550 U.S. at 555).

To satisfy Rule 9(b), a false claims plaintiff "must, at a minimum, describe the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby." United States ex rel. Wilson v. Kellogg Brown & Root, Inc., 525 F.3d 370, 379 (4th Cir. 2008) (quoting Harrison I, 176 F.3d at 784). "These facts are often referred to as the 'who, what, when, where, and how' of the alleged fraud." Id. (quoting United States ex rel. Willard v. Humana Health Plan of Texas Inc., 336 F.3d 375, 384 (5th Cir. 2003)). Together, these pleading requirements ensure a defendant receives "adequate notice of the nature of a claim being made against him." Francis, 588 F.3d at 192.

MiMedx uses the concepts of plausibility and particularity interchangeably without explaining whether it contends this claim is implausible (i.e., Rule 8) or insufficiently particular

(Rule 9(b)), and precisely where the deficiency lies. Cf. Dkt. No. 65-1 at 11–12. This analytical blurring is error because, while particular claims are plausible, plausible claims need not be particular. See, e.g., United States v. Berkeley Heartlab, Inc., 225 F. Supp. 3d 487, 505 (D.S.C. 2016) ("But assuming, arguendo, that Riedel's complaint satisfies Rule 12(b)(6), it falls short of Rule 9(b)'s particularity requirement."); Am. Fed'n of State, Cty. & Mun. Employees Dist. Council 37 Health & Sec. Plan v. Bristol-Myers Squibb Co., 948 F. Supp. 2d 338, 354 (S.D.N.Y. 2013) (noting the plaintiffs did not satisfy Rule 9(b) and "by virtue of the lack of specificity of their pleadings, Plaintiffs cannot survive even the comparatively more forgiving plausibility threshold imposed by Iqbal and Twombly.").

Precedent illustrates that a claim such as this one cannot be dismissed under either Rule 8 or Rule 9. In United States ex rel. Nathan v. Takeda Pharmaceuticals North America, Inc., 707 F.3d. 451 (4th Cir. 2013), a pharmaceutical sales manager fell short of this standard where he alleged an off-label marketing scheme predicated on furnishing doctors with a higher dose of a drug to mislead them into believing it was the only available dose. Id. at 454–55. But the sales manager's conclusion that the scheme caused false claims to be presented relied on a series of problematic assumptions—that doctors who received samples wrote prescriptions for off-label use and that since 93% of the company's sales were for the higher does, at least 90% of the prescriptions identified were "fraudulent." See id. at 459. The Fourth Circuit reasoned this fell short of Rule 9(b)'s requirement, which

> does not permit a False Claims Act plaintiff merely to describe a private scheme in detail but then to allege simply *and without any stated reason for his belief* that claims requesting illegal payments must have been submitted, were likely submitted or should have been submitted to the Government. Rather, Rule 9(b) requires that *some indicia of reliability* must be provided in the complaint to support the allegation that an actual false claim was presented to the government. Indeed, without such plausible allegations of presentment, a relator not only fails to meet

> the particularity requirement of Rule 9(b), *but also does not satisfy the general plausibility standard of Iqbal*.

Id. at 456–57 (quoting United States ex rel. Clausen v. Lab. Corp. of Am., 290 F.3d 1301, 1313 (11th Cir. 2002)) (internal quotations and citations omitted) (emphasis added). Accordingly, when a defendant's actions "*could* have led, but *need not necessarily* have led, to the submission of false claims, a relator must allege with particularity that specific false claims actually were presented to the government for payment." Id. at 457 (emphasis original). Put differently, Nathan merely explains that when an inference of presentment does not necessarily flow from the facts alleged, a pleader can cross that threshold by identifying specific false claims to show presentment occurred. "Of course, whether such factual allegations in a given case meet the required standard must be evaluated on a case-specific basis." Id. at 457–58.

In United States v. Berkeley Heartlab, Inc., 225 F. Supp. 3d 487 (D.S.C. 2016), the district court held an intervened FCA claim predicated on a kickback scheme met the heightened pleading standard because the complaint identified the claims universe and explained why it was tainted by kickbacks. See id. at 498–99. The court explained that identifying each specific claim at the pleading stage was "unnecessary," and looked to other allegations that, when taken as true, supported the conclusion that the submission of false claims was "the necessary, foreseeable, and obvious consequence of these Defendants' participation in the abovementioned schemes." Id. at 499 (citing United States ex rel. DeCesare v. Americare In Home Nursing, 757 F.Supp.2d 573, 589 (E.D. Va. 2010)); see also United States v. Berkeley Heartlab, Inc., 247 F. Supp. 3d 724, 731 (D.S.C. 2017) (rejecting "quibbles" that relator "does not name specific claims and specific patient referrals from physicians who received kickbacks[,]" because the complaint "actually does more—it identifies physicians and practices who were induced…"). These cases (and others) require case-by-case analysis because, by its express terms, all Rule 9(b) requires is notice of "the

circumstances" of the fraud, an objective met by a description of the who, what, when, where, and how. See Wilson, 525 F.3d at 379; see also DiLeo v. Ernst & Young, 901 F.2d 624, 627 (7th Cir. 1990) (analogizing this pleading burden to writing "the first paragraph of any newspaper story."). Thus, while it is admittedly a heightened pleading standard, it is not designed to be an insurmountable one. Instead,

> A court should hesitate to dismiss a complaint under Rule 9(b) if the court is satisfied (1) that the defendant has been made aware of the particular circumstances for which she will have to prepare a defense at trial, and (2) that plaintiff has substantial prediscovery evidence of those facts.

Harrison I, 176 F.3d at 784.

That standard is met here where the Complaint describes the scheme, its participants, and how it is executed. Mr. Vitale's claims are plausible because, as a sales representative, he received direction—some in the form of written correspondence attached to the Complaint—in furtherance of the scheme. See Dkt. No. 1-1 & 1-2. MiMedx's executives also alerted him and his colleagues of when the PAN Foundation fund would open and close (Dkt. No. 1-3, 1-5 & 1-6) which, at a minimum, gives rise to a strong inference of impropriety if it does not corroborate these allegations outright.[3] Finally, if any doubt remains whether the submission of false claims is the necessary, foreseeable, and obvious consequence of this scheme, the Complaint does what Nathan explains will always render a pleading plausible and particular by identifying a specific federally insured patient whose coinsurance was illegally paid as a result of this scheme and furnishes documentary

[3] Cf. United States ex rel. Grenadyor v. Ukrainian Vill. Pharmacy, Inc., 772 F.3d 1102, 1107 (7th Cir. 2014) (Rule 9(b) required the relator allege "either that the pharmacy submitted a claim to Medicare (or Medicaid) on behalf of a specific patient who had received a kickback, or at least name a Medicare patient who had received a kickback (presumably if the pharmacy provided a drug to a Medicare patient it billed Medicare for the cost of the drug minus the copay).").

evidence to corroborate this allegation. See Dkt. No. 1-7. MiMedx has sufficient notice of the claims at issue and the Complaint meets the requirements of Rules 8 and 9(b).

B. A legally cognizable AKS violation has been pled.

MiMedx argues the Complaint fails to plead "remuneration" within the meaning of the AKS because all that is alleged is "(1) MiMedx's donations to PAN and (2) PAN's grants to qualifying patients using MiMedx products." See Dkt. No. 65-1 at 12. The drug company contends the Complaint "contains no allegation that PAN took any steps to ensure that the funds MiMedx donated were preferentially awarded to patients using MiMedx products." Id. This misstates the allegations and nature of the AKS violation here.

The AKS criminalizes the knowing and willful payment of any remuneration to induce the referral of business reimbursable under a federal health benefit program. 42 U.S.C. § 1320a–7b(b). "Any remuneration" means any kickback, bribe, or rebate, direct or indirect, overt or covert, cash or in kind. 42 U.S.C. § 1320a-7b(b)(1). The AKS is construed to cover any arrangement where *one* purpose of the remuneration is to obtain money for the referral of services or to induce referrals. United States v. Ctr. for Diagnostic Imaging, Inc., 787 F. Supp. 2d 1213, 1218 (W.D. Wash. 2011) (citing United States v. Kats, 871 F.2d 105, 108 (9th Cir. 1989)); see also United States v. Greber, 760 F.2d 68 (3rd Cir.), cert. denied, 474 U.S. 988 (1985). Thus, "the appropriate test for whether the waiver of a copay constitutes remuneration is whether the complaint has alleged that at least one of the purposes of the waiver was to induce patient referrals." Berkeley Heartlab, 225 F. Supp. 3d at 513 n.3. To allege a knowing and willful violation of the AKS, a relator need only allege the defendant act with a purpose to commit a wrongful act. See id. at 510.

As explained above and detailed by the Complaint, the scheme at issue is MiMedx's surreptitious manipulation of the PAN Foundation application process to maximize use of its

"charitable" giving to pay coinsurance that will result in federal reimbursement of its products. Simply put, the *quid pro quo* is MiMedx's payment of patient coinsurance, not an inducement of PAN Foundation. Payment of co-pays and coinsurance to facilitate federal reimbursement of the payor's product has always implicated the AKS. See, e.g., Grenadyor, 772 F.3d at 1104 (explaining a discount or refund can become a "kickback" because "it artificially inflates the price that the government pays pharmacies for prescription drugs for Medicare or Medicaid beneficiaries."); Berkeley Heartlab, 247 F. Supp. 3d at 731 (agreements not to charge patients for co-payments and deductibles was actionable FCA claim arising from AKS violations); United States ex rel. Riedel v. Boston Heart Diagnostics Corp., --- F. Supp.3d ---, 2018 WL 4354944 at *9–10 (D.D.C. Sept. 12, 2018) (alleged kickback scheme involving waiver of co-payments and deductibles actionable under AKS); but see United States v. Celgene Corp., 226 F. Supp. 3d 1032, 1057 (C.D. Cal. 2016) (summary judgment on kickback theory with insufficient evidence connecting foundation grants to improper purchase or recommendation for the defendant's drugs). MiMedx's belief otherwise is mistaken.

C. Paying patient copays and coinsurance is a kickback under the AKS unless it falls within a regulatory safe-harbor.

MiMedx contends the allegations do not "support a conclusion that PAN's charitable assistance grants to patients amount to illegal remuneration under the AKS[,]" and that the grants at issue in this case "did not run afoul of the AKS [ ] consistent with guidance from [HHS-OIG] regarding the operation of PAPs." Dkt. No. 65-1 at 7 & 13. To the contrary, HHS-OIG's most recent guidance on the topic directly implicates the scheme here.

On May 21, 2014, the inspector general issued a Supplemental Special Advisory Bulletin regarding Independent Charity Patient Assistance Programs (Supplemental Bulletin), 79 Fed. Reg. 31120, warning that two remuneration arrangements warrant scrutiny under the AKS: "[1] donor

contributions to PAPs (which can also be analyzed as indirect remuneration to patients) and [2] PAPs' grants to patients." Supp. Bulletin, 79 Fed. Reg. at 31121. The Special Bulliten explains "an Independent Charity PAP *must not* function as a conduit for payments or other benefits from the pharmaceutical manufacturer to patients and must not impermissibly influence beneficiaries' drug choices[,]" meaning "pharmaceutical manufacturers and their affiliates *should not exert any direct or indirect influence or control* over the charity or its assistance program." Id. (emphasis added). Of course, MiMedx's purported entitlement to safe harbor protection is premature because "safe harbors are affirmative defenses, and the defendant carries the burden of proof at trial." Berkeley Heartlab, 225 F. Supp. 3d at 511 (quoting United States ex rel. Bartlett v. Ashcroft, 39 F. Supp. 3d 656, 676 (W.D. Pa. 2014) (citing United States v. Rogan, 459 F. Supp. 2d 692, 716 (N.D. Ill. 2006); United States v. Job, 387 Fed. Appx. 445, 455 (5th Cir. 2010) (unpublished); United States v. Norton, 17 Fed.Appx. 98, 102 (4th Cir. 2001) (unpublished))). Still, the drug maker's failure to adequately address this authority implicitly concedes the weakness of its position given the Complaint's quotation, citation, and discussion of the Supplemental Bulletin in conjunction with the operative facts. See Dkt. No. 1 at ¶¶ 33–39. Thus, because MiMedx's conduct directly implicates the potential abuses described in the Special Bulletin, it is not entitled to safe harbor protection if the allegations are proven true.

MiMedx's only response is to misleadingly cite HHS-OIG guidance *predating* the Special Bulletin. For example, MiMedx cites November 2005 guidance from HHS-OIG giving cautious approval of PAP charity programs as if it is the final authority on the matter. See Dkt. No. 65-1 at 7 (citing HHS-OIG, Special Adv. Bulletin on PAPs, 70 Fed. Reg. 70623–24 (Nov. 2005), and arguing "[w]hile OIG has identified certain features of PAPs that could raise concerns under the AKS, none of those features are alleged to be present here."). Likewise, MiMedx quotes from a

2007 Advisory Opinion (No. 07-18) as evidence "that donations to PAN by manufacturers 'should raise few, if any, concerns about improper beneficiary inducements." Dkt. No. 65-1 at 14. However, taken in context, the advisory opinion (attached to MiMedx's memorandum) sought to highlight the need for independence, not dispel kickback concerns altogether, noting: "*Under a properly structured program*, such donations should raise few, if any, concerns about improper beneficiary inducements." Dkt. No. 65-2 at 10 (emphasis added). The advisory opinion discusses some aspects of that "proper structure" that are absent here:

> First, no donor or affiliate of any donor exerts direct or indirect control over the Foundation or its programs. …
>
> Second, the Foundation awards assistance in a truly independent manner that severs any link between donors and beneficiaries.

Id. (underline original).

Instead, MiMedx should have addressed the Supplemental Bulletin issued in 2014 because it directly speaks to the issue here by cautioning that independent PAP charities "must not function as a conduit for payments[.]" Supp. Bulletin, 79 Fed. Reg. at 3112. Further highlighting its concern over illegal coordination, HHS-OIG warns that disease funds that cover only a single product or products by a single manufacturer "will be subject to scrutiny" because of the risk of "steering patients to the drugs for which assistance is available[,]" which, "increases the likelihood *that the donors could use the PAPs as improper conduits to provide a subsidy to patients who use the donors' own products*." Id. (emphasis added). That is precisely what has occurred here, but instead of addressing these concerns head-on MiMedx's obscurely argues the Complaint should have instead addressed some aspect *of PAN Foundation's program*. See Dkt. No. 65-1 at 14–18. PAN Foundation's conduct has no bearing on this claim as PAN Foundation has not been joined as a defendant and the allegations leave open the possibility it is an unwitting participant in MiMedx's

manipulation scheme. What MiMedx fails to do is convincingly explain why, accepting all allegations as true, its own conduct is not a violative of the AKS and FCA.

D. Arguments that mischaracterize the allegations cannot be credited as grounds for dismissal.

MiMedx argues Mr. Vitale has not alleged facts sufficient to establish the PAN Foundation grants to patients are "illegal 'indirect' remuneration from MiMedx to those patients[,]" because the scheme at issue is "inconsistent with the way that Relator describes how PAN assistance funding worked." Dkt. No. 65-1 at 12. Again, MiMedx misses the point. Relying on HHS-OIG guidance, the Complaint describes two circumstances: (1) the way PAP foundation assistance is *supposed to work* and (2) MiMedx's scheme to coopted that system for its own benefit. Compare Dkt. No. 1 at ¶¶ 25–40 & 104–14, with id. ¶¶ 115–66. Mr. Vitale does not allege that PAP assistance is *per se* forbidden; instead, it is MiMedx's perversion of that system that places this scheme outside any recognized safe harbor and violates the AKS.

Moreover, MiMedx urges the Court to draw unsupported inferences that go beyond the facts alleged. The drug company argues the decision to use its products "was made *before* any assistance from PAN to the patient was ever requested, let alone provided, rendering it impossible that the payment from PAN to the patient was a form of remuneration intended to induce the use of MiMedx's products." Dkt. No. 65-1 at 13. This claim should be rejected for two reasons. First, even assuming it is correct, MiMedx cites no authority explaining why this fact is of any consequence. FCA liability attaches "where the defect in the claim is material and where the defendant acts knowingly." United States ex rel. Westmoreland v. Amgen, Inc., 812 F. Supp. 2d 39, 46 (D. Mass. 2011). The prospect that a physician ordered the MiMedx product without knowing whether the patient would receive a PAP grant is immaterial so long as MiMedx

knowingly corrupted the claim by coordinating its "charitable" contributions with patient PAP grant applications.

Second, Mr. Vitale disputes MiMedx's reading of the Complaint as an adverse inference to which it is not entitled. Properly read, the Complaint indicates patients would not have received *any* biologic product but-for Mr. Vitale and other MiMedx reps employing a sales strategy to (1) identify prospective patients, (2) complete and submit insurance verification requests (IVRs) to obtain pre-approval from federal payors, (3) complete and submit PAP grant applications for patients, and, upon notice a grant was approved, (4) notifying clinics to ensure the procedure was scheduled. See Dkt. No. 1 at ¶¶ 63–67, 73–81, 94–103 & 131–59. Thus, to the extent an inference is warranted, it supports the opposite conclusion: but-for MiMedx's PAP-grant scheme, most patients would *not* have received MiMedx products because those patients would not obtain IVRs or PAP grants and therefore could not afford the product. Moreover, but-for the effort by MiMedx reps to obtain PAP grants for patients, the clinic would be unable to charge for the sale and application of the product—a lucrative billing opportunity for the customer clinic. See id. ¶ 67 ("MiMedx reps argued to program directors and private physicians that the use of its products—far more expensive than most wound care products—would generate profits for the customer, which charge for the sale and application (i.e., grafting) of MiMedx products at a higher rate than for the use of standard of care products.").

E. Use of a drug need not be "medically unnecessary" to be tainted by a kickback and actionable under the FCA.

MiMedx suggests there is no wrongdoing because Mr. Vitale "does not allege that the use of EpiFix was medically necessary for any patient." Dkt. No. 65-1 at 10. Medical necessity is irrelevant to this claim. Compliance with the AKS is a material condition of payment under federal insurance programs such that violating the AKS gives rise to a false claim. See Westmoreland,

812 F. Supp. 2d at 54 (collecting cases). The claim need not be medically unnecessary (i.e., factually false) because the kickback scheme renders it legally false under the FCA. See United States ex rel. Kester v. Novartis Pharm. Corp., 43 F. Supp. 3d 332, 360–61 (S.D.N.Y. 2014) (legally false claims are those tainted by a statutory, regulatory, or contractual violation made in connection with the claim and rendering it ineligible for reimbursement).

F. Unlike other aspects of a claim, intent need not be pled with specificity.

MiMedx suggests the Complaint is deficient because it makes "general allegations" concerning whether MiMedx "acted with criminal intent (as required to establish an AKS violation). See Dkt. No. 65-1 at 6–7. This is incorrect because Rule 9(b)'s heightened standard does not apply to allegations concerning state of mind: "Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b).

* * *

For the reasons explained above, MiMedx's challenge to the sufficiency of the pleadings should be rejected and the Court should hold the Complaint alleges the who, what, where, when, and how of the fraud such that Rule 9(b) is satisfied and MiMedx has sufficient notice of the allegations such that it can file a responsive pleading.[4]

II. The public disclosure bar poses no obstacle because the purportedly disqualifying action was never disclosed in a hearing to which the government was a party and did not include the essential elements of this fraud.

MiMedx argues this claim is barred by United States ex rel. Montecalva v. MiMedx Goup, Inc., C.A. No. 1:14-cv-01260-RCL, (D.D.C. filed July 24, 2014, unsealed Oct. 6, 2015), which

[4] However, if the Court were to disagree, the proper remedy is an order allowing Mr. Vitale to file an amended complaint, not dismissal with prejudice. See, e.g., Ctr. for Diagnostic Imaging, Inc., 787 F. Supp. 2d at 1215 (granting motion to dismiss in part but also granting relator leave to amend); United States v. TEVA Pharm. USA, Inc., No. 13 CIV. 3702 (CM), 2016 WL 750720, at *1 (S.D.N.Y. Feb. 22, 2016) (giving the relator 30 days to file an amended complaint).

MiMedx argues alleged free samples, in-office services, and speaker fees by MiMedx, and misconduct by PAN Foundation. See Dkt. No. 65-1 at 23–24. The current iteration[5] of the FCA's public disclosure bar requires that, unless opposed by the government or where the relator is the "original source" of the information, a district court must dismiss an action or claim "if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed-- (i) in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party;" (ii) in certain government reports; or by the news media. 31 U.S.C. § 3730(e)(4). MiMedx argues Montecalvo is a disqualifying public disclosure because both mention or discuss meals and entertainment, speaker payments, free services, reimbursement access, and a "relationship with PAN" that MiMedx contends was "sufficient to alert the government to the potential improper conduct" alleged here. See Dkt. No. 65-1 at 25–28. This argument should be rejected for two reasons.

First, even assuming the allegations are identical (they are not), Montecalvo is not a public disclosure because the allegations were not disclosed in "a hearing" in which the Government was "a party[.]" See 31 U.S.C. § 3730(e)(4)(i). As MiMedx notes, in Montecalvo the government "ultimately declined to intervene" and the relator "subsequently dismissed the complaint[.]" Dkt. No. 65-1 at 23–24. As this Court has explained, the government is not a "party" to a *qui tam* action

[5] Prior to March 23, 2010, the FCA stripped jurisdiction over actions based upon publicly disclosed allegations unless the action was brought by the Attorney General or the *qui tam* relator was the original source of the disclosed information. See 31 U.S.C. § 3730(e)(4)(A) (2005); see also United States ex rel. May v. Purdue Pharma L.P., 737 F.3d 908, 914 (4th Cir. 2013) (discussing). This version of the bar, "if applicable, divested the district court of subject-matter jurisdiction over the action." Id. at 916. (citing Rockwell Int'l Corp. v. United States, 549 U.S. 457, 468– 69 (2007)). Section 3730(e)(4) was subsequently amended to require a district court "shall" dismiss an action based upon a public disclosure "unless opposed by the Government[.]" 31 U.S.C. § 3730(e)(4)(A) (2010). Congress's removal of the jurisdictional language from the statute indicated that, post-amendment, "the public- disclosure bar is no longer jurisdictional." May, 737 F.3d at 916.

until it intervenes (see Dkt. No. 37 at 4 (citing United States ex rel Eisenstein v. City of New York, 556 U.S. 928, 933 (2009)), and MiMedx points to no "hearing" sufficient to satisfy the public disclosure bar. Even though the Montecalvo docket was unsealed, MiMedx also points to no government or public news report capable of implicating subsections (ii) and (iii) of the bar. Thus, the only possible disqualifying disclosure claimed by MiMedx is under subsection (i), "in a Federal criminal, civil, or administrative hearing in which the Government or its agent is a party[,]" which, according to MiMedx's own representations, is not met here.

Second, the scheme at issue here is not "substantially the same allegation[ ] or transaction[ ]" than the allegations in Montecalvo, because nowhere in that complaint is the very specific PAP grant application and funding scheme described by Mr. Vitale. Claiming no established standard in this Circuit (see Dkt. No. 65-1 at n.10), MiMedx looks to foreign precedent for guidance. See Dkt. No. 65-1 at 24–25.[6] In United States ex rel. Beauchamp v. Academi Training Ctr., 816 F.3d 37 (4th Cir. 2016), the Fourth Circuit considered whether the public disclosure bar blocked an amended complaint that incorporated allegations in a media report about another dismissed FCA case. Id. at 41. While its decision turned on an amendment's effect on the timing of the disclosure, the Fourth Circuit admonished the district court for failing "to analyze the public-disclosure bar on the basis of the relevant fraud alleged." Id. at 44–45 ("The Supreme Court in [Rockwell Int'l Corp. v. United States, 549 U.S. 457 (2007)] focused on the relator's last pleading only because that was where the relevant fraud, the improper-waste-mixture theory, had been pled."). The authority cited by MiMedx also looks to discern whether the essential elements of the fraud were

[6] Citing Citynet, LLC on behalf of United States v. Frontier W. Va. Inc., 2018 WL 1582527 (S.D. W. Va. Mar. 30, 2018), United States ex rel. Advocates for Basic Legal Equal., Inc. v. U.S. Bank, N.A., 816 F.3d 428, 431 (6th Cir. 2016), cert denied, 137 S.Ct. 2180 (2017), In re Plavix Mktg., Sales Practices & Prod. Liab. Litig., 123 F. Supp. 3d 584, 598 (D.N.J. 2015), and United States ex rel. Osheroff v. Humana, Inc., 776 F.3d 805 (11th Cir. 2015).

publicly disclosed. See, e.g., Advocates for Basic Legal Equal., 816 F.3d at 430 ("ABLE's case *rests on* two factual allegations …" (emphasis added)); Osheroff, 776 F.3d at 814 ("Mr. Osheroff's *essential allegation* is that the clinics provided a wealth of free services. The public sources fully disclose that the defendant clinics provided such services…." (emphasis added)); In re Plavix, 123 F. Supp. 3d at 599 ("These allegations, which tend to show that Defendants had knowledge that their claims were false and were intended to have physicians make false claims to the government involving Plavix prescriptions, provide '*essential elements* of the fraudulent scheme' which were missing from the prior disclosures." (emphasis added)).

The essential element distinguishing this claim from Montecalvo is the scheme to manipulate the submission of PAP application grants and coordinate charitable giving that ensured those funds maximize the prospect of federal reimbursement. That is the only theory Mr. Vitale has ever sought to proceed under and it is entirely absent from the Montecalvo allegations. Instead, the totality of the 182-page complaint's discussion of PAN Foundation is a fleeting mention in a laundry list of other purported misconduct:

> 121. MiMedx provides representatives, paid by MiMedx and at no charge to medical providers, who review EpiFix patients' information on medical providers' computers and qualify those patients for coverage by Government Health Care Programs for application of and treatments relating to EpiFix.
>
> […]
>
> c. Moreover, *on information and belief*, Mr. Moore routinely uses the Patient Access Network ("PAN") Foundation, an organization that pays co-payments, by logging into the "PAN Portal" as if he represents the medical provider and puts patients through who may not be eligible for coverage.

Montecalvo, Doc. 1 at ¶ 121.c (emphasis added). This sole reference to PAN Foundation fails to describe any aspect of the scheme in this case and it is insufficient to put the government (or

anyone) on notice of the who, what, where, when, and how of *this* fraud where it is predicated on "information and belief" by a sales representative working for a MiMedx competitor. See id. ¶ 16.

Finally, because there is no public disclosure, the original source exception does not apply here an need not be considered. Cf. Dkt. No. 65-1 at 29–30.

CONCLUSION

For the foregoing reasons, the motion should be denied, and this action should proceed to discovery and trial.

Respectfully submitted by,

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